

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the claims

Claims 1-22 were previously cancelled and claims 25-34 and 36-42 are now cancelled. Claim 23 is amended, and incorporates subject matter from the newly depended claims which previously depended from claim 23.

No new matter is added. The foregoing amendments are made solely to advance prosecution and without acquiescence to any objection or rejection, and without disclaimer of any cancelled subject matter. Applicant reserves the right to pursue cancelled subject matter in continuing applications with the same rights of priority as the present application.

Upon entry of the foregoing amendments, claims 23, 24, 35 and 43 are pending, and claims 23, 24, and 35 are under examination. These claims are presented for reconsideration.

II. Withdrawn rejections

Applicants acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 102(b) and the enablement and written description provisions of 35 U.S.C. § 112, first paragraph. Office Action at pages 2-3.

III. Provisional objection under 37 C.F.R. § 1.75

Cancellation of claim 33 renders moot the provisional objection to claims 28 and 33, for being substantially duplicative. Office Action at page 3.

IV. Rejection under 35 U.S.C. § 112, first paragraph

Claims 34 and 35 are rejected as not enabled for failing to fulfill all requirements under the Budapest Treaty. Claim 34 is cancelled. With regard to claim 35, reciting monoclonal antibody BC-05a, Applicant submits herewith a Declaration of Biological Deposit, according to the Budapest Treaty. Applicant believes that the rejection is overcome, and respectfully requests its reconsideration and withdrawal.

V. Rejections under 35 U.S.C. § 103(a)

Claims 23-42 are alleged to be rendered obvious by the combination of Schenk (WO 00/72880 A2), disclosing a method of treating Alzheimer's disease by administration of an antibody against amyloid β , in view of Suzuki (U.S. Patent No. 5,750,349), disclosing specific antibodies that are within the scope of the presently claimed methods (*e.g.*, BC-05a). Office Action at pages 4-8. The Examiner asserts, at page 7 of the Office Action:

As evidenced by Suzuki et al., the artisan of ordinary skill would have known that the C-terminal antibodies disclosed therein could be used in methods of developing treatments for Alzheimer's disease. Furthermore, it would have been reasonable to predict that the antibodies of Schenk could be used in methods of developing treatment for Alzheimer's disease. ... the artisan of ordinary skill would have found it obvious to try to use Suzuki's antibodies in Schenk's treatment methods.

Applicant respectfully traverses the rejection, for at least the following reasons:

A. Teaching away from the combination

Under *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007), there must be a "reason or suggestion" to combine the references. Such a reason or suggestion can be undermined by clear teaching away.

Schenk teaches away from combining Schenk and Suzuki. Schenk's Example XI showed A β -specific polyclonal antibody (raised by immunization with aggregated AN1792 (A β 1-42)), and A β -specific monoclonal antibodies 2H3 (directed to A β residues 1-12), 10D5 (directed to A β residues 1-16), 266 (directed to A β residues 13-28), and 21F12 (directed to

A β residues 33-42). See page 83, lines 14-24 of Schenk. Among these antibodies, the polyclonal antibody raised against AN1792 and the monoclonal antibodies 2H3 and 10D5, all of which are *not* directed to the C-terminus region of A β , showed treatment effects such as reduced A β levels in the cortex, hippocampus and cerebellum in animals treated. See page 92, lines 1-5 and Tables 13-15 of Schenk. On the other hand, the monoclonal antibody 21F12, which *is* directed to the C-terminus region of A β , did not show such treatment effects. See Tables 13-15 of Schenk. In view of this disclosure of Schenk, the artisan of ordinary skill would understand that A β -C-terminus-region-specific antibody could *not* be used for reducing A β levels in the cortex, hippocampus and cerebellum and thus could not be used for treating Alzheimer's disease. Therefore, the artisan of ordinary skill would not use Suzuki's antibody, which is directed to the C-terminus region of A β , instead of Schenk's antibody, which is not directed to the C-terminus region of A β , for treating Alzheimer's disease.

B. Unexpected results

Not only is there no reason or suggestion to combine Suzuki with Schenk, the present invention demonstrates unexpected results. The present specification shows advantageous effects of the present invention. For example, administration of BC-05a, which is directed to the C-terminus region of A β , resulted in removal and amelioration of the deposition of cerebral A β . Page 24, lines 18-25 of the present specification states that "any change in the soluble A β _x-40 level in the brain was not observed but a reducing tendency of the insoluble A β _x-40 level was observed. The A β _x-42 level in the brain was significantly increased for the soluble fraction but a reducing tendency for the insoluble fraction was observed." Thus, the presently claimed antibodies were able to preferentially remove the type of A β that is associated with Alzheimer disease. This result is unexpected, especially in view of Schenk.

C. Summary

Accordingly, pending claims 23, 24 and 35 are not obvious over Schenk and Suzuki. Applicant respectfully requests reconsideration and withdrawal of the rejection.

CONCLUSION

It is believed that the present application is now in condition for examination and expeditious allowance. Favorable consideration is respectfully requested.

Examiner Emch is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to credit any overpayment and to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the same deposit account. If any extension of the response deadline is needed, then applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes charging the relevant fee(s) to the deposit account.

Respectfully submitted,

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By 

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